UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *County of Suffolk v. Abbott Labs., et al.*, (E.D.N.Y. No. CV-03-229)	

RESPONSE OF AMGEN INC. TO SUFFOLK COUNTY'S SUBMISSION REGARDING METHODOLOGY USED TO ESTIMATE AWP SPREAD AND ADDITIONAL INFORMATION REGARDING DEFENDANTS

Suffolk County's "additional information" regarding Amgen, apart from being improper on its face,[1] is inaccurate and misleading. Suffolk's information is anchored to virtually identical allegations filed by the same lawyers and fraught with the same shortcomings as those in the Amended Complaint in this case. Worst yet, much of the information is just plain wrong, and mischaracterizes the nature and/or existence of so-called "investigations" involving Amgen. In either case, the submission of such information cannot save Suffolk's Amended Complaint.

First, Amgen is not, as Suffolk's counsel asserts in his affidavit, under investigation by either the U.S. Department of Justice and/or the Office of Inspector General of

[1] As the Response of the "Suffolk 13 + 6" to Suffolk's Supplemental Filing explains, Suffolk's "additional information" is improperly before the Court and should not be considered in the first instance. *See* Response of the Suffolk 13 + 6 Challenging Suffolk County's Supplemental Filing in Response to the Court's October 26, 2004 Order. This memorandum is submitted on behalf of Amgen Inc. to respond to such additional information, to the extent it is directed at Amgen, should the Court choose to consider it.

the Department of Health and Human Services. *See* Affidavit of Aaron D. Hovan ("Hovan Aff."), Ex. A. Similarly, the reference to investigations by the Attorneys General of Pennsylvania and Wisconsin appears to reference the filing of complaints by those states, which are based upon factual allegations that are nearly identical to those in this case, and that either are subject (as in Pennsylvania) or will be subject (as in Wisconsin) to their own motions to dismiss.

Second, Suffolk points to the fact that Amgen "has been sued in the private class action Amended Master Consolidated Complaint and by the City of New York and Counties of Rockland and Westchester. True enough. The problem is, all three cases were brought by Suffolk's counsel here, and their copycat claims, not surprisingly, suffer from precisely the same defects as Suffolk's Amended Complaint. Pointing to other, equally lacking complaints does nothing to bolster Suffolk's case. Similarly, the Amended Master Consolidated Complaint has been twice dismissed against Amgen, and Amgen's third motion to dismiss – based on many shortcomings similar to those at issue here – is currently pending before the Court.

Third, Amgen is not "under investigation" by the Senate Finance Committee ("Committee") for abuse of the Nominal Price Exception. By letter dated April 29, 2004, a copy of which is attached hereto as Exhibit 1, Amgen – along with numerous other manufacturers – was simply asked to provide information in connection with the Committee's efforts "to assess how frequently the Nominal Price Exception to Best Price reporting is used," as part of a "study" to determine whether "refinements should be made to the existing statutory language." Ex. 1 at 1-2. Significantly, the letter – which was sent to 19 pharmaceutical companies – was not based upon any allegation or perception of wrongdoing. Instead, recipients were selected based upon total sales and type of product manufactured: "In order to ensure that the Committee has sufficient information on which to base its determinations, we are inquiring about drugs in the

eight most popular classes to those manufacturers that ranked among the top twenty according to sales in 2003." *Id.* at 2.

Fourth, and as this Court previously recognized in dismissing the AMCC against Amgen, the 1993 OIG Report to which Suffolk's counsel refers did not involve an "investigation" and does not support an inference of fraud. *See Citizens for Consumer Justice v. Abbott Labs.*, No. 1:01-CV-12257-PBS (D. Mass. June 9, 2004) (electronic order granting Amgen's Motion for Reconsideration and dismissing the AMCC against it after rejecting plaintiffs' reliance on the 1993 OIG report). Instead, the report, which focused solely on the statutory and non-AWP-based reimbursement rate for Epogen®, was part of a routine audit performed by OIG's audit division (as opposed to its Office of Investigations). As the text of the report itself makes plain, the review was not conducted as a result of any alleged impropriety and did not render any such finding. Instead, it was conducted as part of an ongoing review to determine whether initial assumptions regarding sales volumes, revenues, and reimbursement levels were accurate or needed to be revised. Based upon the analysis conducted, OIG determined and recommended to the Health Care Financing Administration ("HCFA"), the predecessor to the Centers for Medicare and Medicaid Services ("CMS") that the Epogen® reimbursement methodology be refined.

CONCLUSION

For the foregoing reasons, and for the reasons set forth in Certain Defendants' Response to Suffolk's affidavit, Amgen requests that the remaining claims against it in Suffolk's Amended Complaint be dismissed.

Respectfully submitted,

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